

formulas for your future



APR 13 2004

March 29, 2004

P.O. Box 199

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FDA
200 C Street, SW
Washington, DC 20204

110 South Garfield

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

Mt. Angel, OR 97362

In compliance with the Dietary Supplement Health and Education Act of 1994, **Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362**, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

503-845-9223

1-800-547-0273

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Carbo Smasher™	Phaseolamin 2250™ 1000 mg. Bitter Melon 300 mg. Gymnema Sylvestre 150 mg.	Supports weight loss goals in conjunction with a healthy diet and exercise. <i>Please see attachment 1</i>

FAX 503-845-6364

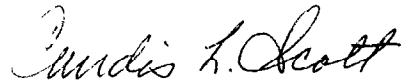
975 0162

LET

14016

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and misleading.

Sincerely,

A handwritten signature in black ink, reading "Candis L. Scott". The signature is written in a cursive, flowing style with a large initial 'C'.

Candis L. Scott
CEO Highland Laboratories

Attachment 1
Highland Laboratories

Carbo Smasher™

Remember when cars had carburetors? That's usually what guys were checking out under the hood of their old jalopies. It was a metal gizmo that sat on top of the engine, mixing fuel and air for the engine's combustion cylinders Vroom Vroom.

Wouldn't be nice if humans had carburetors for carbohydrates? Or better yet, a computerized fuel injection system, like on newer cars, which makes carburetors obsolete?

Instead, humans rely on a variety of other mechanisms to combat excessive carb intake: exercise, discipline, diets, supplements, prescription drugs and even surgery.

In a healthy body, insulin acts kind of like a fuel injection system, by controlling the amount of glucose (the sugar derived from carbs) in the blood and the rate at which glucose is taken into the cells. Human cells, like an engine's cylinders, convert the fuel (glucose) into energy.

While the quantity of carbs you ingest is part of the equation, the bigger picture is how your body metabolizes it. In most cases, keeping carbs in balance with a healthy diet and exercise are the ticket. Why? Because glucose not transformed into useful energy ends up as body fat and causes havoc in the rest of the body as well.

Carbo Smasher was designed to help you attain your desired weight goals in conjunction with a healthy diet and exercise.

- ***Phaseolamin 2250™*** is made from white kidney beans (*phaseolus vulgaris*). Research over the past 60 years has determined that certain of these beans' components inhibit *amylase*, an enzyme in the body that turns starch (carbs) into glucose (sugar).¹ Carbs not converted into glucose are excreted naturally.
- ***Bitter Melon***, also known as balsam pear, is a tropical fruit used in folk medicine in Asia, Africa and South America. It has properties that demonstrate hypoglycemic activity, including an insulin-like polypeptide known as p-insulin (the 'p' is for plant)²
- ***Gymnema Sylvestre*** hails from tropical India where it has been used for centuries.

Sources:

1. Meiss, Dennis, PhD, Phaseolamin 2250: New, Standardized Starch Neutralizer Evolves from 60 Years of Research, Health Products Business magazine, 2001.
2. Werbach, MR; Murray, MT, A sourcebook of clinical research, Third Line Press, 1994, pg. 139 - 141